IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

DEBRA WISE, et al.,

Plaintiffs,

v. **CIVIL ACTION NO. 2:12-cv-01378**

C. R. BARD, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Motions *in Limine*)

Pending before the court are the following motions *in limine* brought by the plaintiffs, Debra and Ronald Wise: (1) Evidence Relating to the United States Food and Drug Administration ("FDA") [Docket 128]; (2) Evidence Relating to Testing Conducted on Products Not at Issue in this MDL [Docket 129]; (3) Any Argument or Testimony Representing or Implying that Chevron Phillips Employee Frank Zakrzewski Said That There Was "No Scientific Basis" or "No Evidence" for the Medical Application Caution in the Marlex HGX-030-01 MSDS [Docket 132]; (4) Other Lawsuits Against the Implanting Surgeon [Docket 133]; (5) Empty Chair Defense [Docket 170]; (6) AUGS/SUFU SUI Sling "Position Statement" [Docket 171]; and (7) Other Manufacturers' Pelvic Repair Mesh Products and Unrelated Bard Product Experience [Docket 172].

Pending before the court are the following motions *in limine* brought by the defendant, C. R. Bard, Inc. ("Bard"): (1) Motion to Preclude Any Evidence or Argument Concerning Any Material Safety Data Sheet for Polypropylene Resin and the Manner by Which Bard Procured Polypropylene Resin from Suppliers [Docket 175]; (2) Motion to Preclude Any Evidence or Argument Concerning Unrelated Business Issues, Investigations, Alleged Bad Acts, or Alleged

"Illegal Activity" [Docket 175]; (3) Motion to Preclude Any Evidence or Argument that Bard Owed or Breached an Independent Duty to Conduct Additional Testing or Inspection [Docket 175]; (4) Motion to Preclude Any Evidence or Argument Concerning Post-Implant Regulatory Communications and Developments [Docket 175]; (5) Motion to Preclude Any Evidence or Argument Concerning Bard's Decision to Stop Selling the Avaulta Products or Suggesting the Avaulta Products Were Recalled or Withdrawn [Docket 175]; (6) Motion to Preclude Any Evidence or Argument Concerning Foreign Regulatory Actions [Docket 175]; (7) Motion to Preclude Any Evidence or Argument that Bard Owed or Breached a Duty to Warn Plaintiff Directly or Bard Owed or Breached a Duty to Train Plaintiff's Physician [Docket 175]; (8) Motion to Preclude Any Evidence or Argument Related to Product Complaints, Adverse Event Reports, and Medical Device Reports Concerning Patients Other Than Plaintiff [Docket 175]; (9) Motion to Preclude Any Evidence or Argument Concerning Other Lawsuits Involving Mesh [Docket 175]; (10) Motion to Preclude Any Evidence or Argument Concerning Marketing or Promotional Activity That Did Not Impact Plaintiff's Prescribing Physician [Docket 175]; (11) Motion to Preclude Any Evidence or Argument That the Avaulta Products Can Cause Persistent Delayed Healing, Dehiscence, Abscess or Other Alleged Complications Not Experienced by Plaintiff [Docket 175]; (12) Motion to Preclude Any Evidence or Argument Concerning Bard's Intent, Motives, and Ethics [Docket 175]; (13) Motion to Preclude Any Evidence or Argument Concerning the Alleged Pain, Suffering, and/or Impact of Plaintiffs' Alleged Injuries on Their Children, Family, or Friends [Docket 175]; (14) Motion to Preclude Any Argument or Evidence of a Relationship Between Polypropylene or the Avaulta Plus System and Cancer [Docket 175]; (15) Motion to Preclude Inflammatory and Prejudicial Statements or Evidence During Trial [Docket 175]; (16) Motion to Preclude Any Evidence or

Argument Concerning Parties' Litigation Conduct [Docket 175]; (17) Motion to Preclude Any Evidence or Argument Concerning Bard's Financial Information or Condition [Docket 175]; and (18) Motion to Preclude Argument or Evidence of the Health of Plaintiff's Parents and Plaintiff's Role in Caring for her Parents [Docket 175].

For the reasons set forth below, the plaintiffs' Motion *in Limine* No. 1 [Docket 128] is **GRANTED**; the plaintiffs' Motion *in Limine* No. 2 [Docket 129] is **DENIED**; the plaintiffs' Motion *in Limine* No. 3 [Docket 132] is **DENIED**; the plaintiffs' Motion *in Limine* No. 4 [Docket 133] is **DENIED**; the plaintiffs' Motion *in Limine* No. 5 [Docket 170] is **DENIED**; the plaintiffs' Motion *in Limine* No. 6 [Docket 171] is **DENIED**; and the plaintiffs' Motion *in Limine* No. 7 [Docket 172] is **DENIED**.

Additionally, Bard's Motions *in Limine* No. 4, 9, 11, and 14 [Docket 175] are **GRANTED**; Bard's Motions *in Limine* Nos. 15, 16, and 17 [Docket 175] are **GRANTED in part** and **DENIED in part**; and the following of Bard's Motions *in Limine* are **DENIED**: 1–3, 5-8, 10, 12, 13 and 18 [Docket 175].

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 10,000 of which are in the Bard MDL, MDL 2187. In this particular case, the plaintiff, Debra Wise, was surgically implanted with the Avaulta Plus Anterior Support System and the Avaulta Plus Posterior Support System (collectively "Avaulta Plus"), mesh products manufactured by Bard to treat POP. (*See* Short Form Compl.

[Docket 1], at 2).[1] The plaintiff received her surgery in West Virginia. (*Id.* at 4). The plaintiff claims that as a result of implantation of the Avaulta Plus, she has experienced multiple complications, including vaginal spasms, damage to her ureter, vagina, and rectum, kidney reflux, urinary tract infections, chronic constipation, dyspareunia (pain during sexual intercourse), lower pelvic pain, incontinence, and kidney stones. (*See* Pl. Fact Sheet [Docket 102-9], at 7). The plaintiff alleges negligence, strict liability for design defect, strict liability for manufacturing defect, strict liability for failure to warn, breach of express warranty, breach of implied warranty, and punitive damages. (Short Form Compl. [Docket 1], at 4). Additionally, the plaintiff's husband, Ronald Wise, alleges loss of consortium. (*Id.*). The instant motions *in limine* involve the parties' efforts to exclude or limit certain evidence, arguments, and testimony at trial.

II. The Plaintiffs' Motions *in Limine*

a. Evidence Relating to the FDA

First, the plaintiffs "move to preclude any argument, evidence or testimony relating to the FDA." (Pls.' Mot. *in Limine* No. 1 [Docket 128], at 1). In every previous case in these MDLs, this court has excluded evidence regarding the FDA 510(k) clearance process of the product at issue.[2] I see no reason to depart from this position, which I succinctly described in *In re C. R.*

[1] The present case is part of Wave 1 of the Bard MDL, MDL 2187. (Pretrial Order # 118 (Docket Control Order for Selection and Discovery of 200 Cases [Docket 15]). Because the parties agree that the Southern District of West Virginia is the proper venue, I set this case for trial in the Southern District. (*See* Am. Joint Submission, MDL 2187 [Docket 1004], at 8; *see also* Order [Docket 63]).

[2] *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 756 (S.D. W. Va. 2014) (granting a motion to exclude evidence of the 510(k) process because 510(k) clearance "does not go to whether the [mesh] products are safe and effective") (internal quotations omitted); *Eghnayem, et al. v. Boston Scientific Corp.*, No. 2:13-cv-07965, 2014 WL 5461991, at *60 (S.D. W. Va. Oct. 27, 2014) ("I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy."); *Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *64 (S.D. W. Va. Oct. 17, 2014) (same); *Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *37 (S.D. W. Va. Sept. 29, 2014) (same); *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3882186, at *3 (S.D. W. Va. Aug. 7, 2014) ("I now hold that the evidence of the FDA's 510(k) process is inadmissible in this case."); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 1883784, at *1 (S.D. W. Va. May 12, 2014) (same); *Cisson, et al. v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 3821280, at *7 (S.D. W. Va. July 23, 2013) ("The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no operative

Bard, Inc.:

> After reviewing the motions, responses, and exhibits thereto, I **FIND** that evidence as to the FDA's 510(k) process and lack of enforcement action should be excluded under Federal Rule of Evidence 403 because of the danger of misleading the jury, confusing the issues, and unfair prejudice. Given the parties' filings throughout this case, it is abundantly clear that there would be a substantial mini-trial on the 510(k) process and enforcement should it be allowed. In short, this evidence poses a substantial risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims, and if such evidence comes in via expert testimony, the expert would effectively be offering a legal conclusion.

No. 2:10-CV-01224, 2013 WL 3282926, at *2 (S.D. W. Va. June 27, 2013). On these grounds, I **GRANT** the plaintiffs' Motion *in Limine* No. 1.

b. Evidence Relating to Testing Conducted on Products Not at Issue in this MDL

Next, the plaintiffs "move to preclude any argument, evidence or testimony relating to testing conducted on products not at issue in this MDL[.]" (Pls.' Mot. *in Limine* No. 2 [Docket 129], at 1). The plaintiffs contend that "[b]ecause Bard never conducted biocompatibility testing on the Avaulta Plus/Solo or Align products, Bard should not be allowed to present any evidence or argument improperly suggesting it had." (*Id.* at 4). In response, Bard explains that it "intends to show the extensive testing performed on similar devices marketed and in clinical use at the time the Avaulta was designed." (Bard's Opp. to Pls.' Mot. *in Limine* No. 2 [Docket 191], at 1). This issue is more appropriately suited for trial.[3] I expect counsel to be familiar with the Federal Rules of Evidence and therefore not offer evidence he or she knows is inadmissible. I refuse to validate the plaintiffs' effort to elicit an order from me simply requiring that basic rules be followed. Accordingly, the plaintiffs' Motion *in Limine* No. 2 is **DENIED**.

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interaction with state tort laws.") (internal citation omitted). (*See also* Mem. Op. & Order [Docket 280], at 12 (concluding that the plaintiff's claims are not preempted by the 510(k) clearance of the Prolift because 510(k) clearance does not speak to the safety or effectiveness of a product)).

[3] In the *Cisson* trial, I allowed Bard's non-retained corporate expert, Roger Darois, to offer similar testimony on biocompatibility testing. (*See* Cisson Trial Tr. [Docket 1912], at 161–63).

c. Any Argument or Testimony Representing or Implying that Chevron Phillips Employee Frank Zakrzewski said that there was "No Scientific Basis" or "No Evidence" for the Medical Application Caution in the Marlex HGX-030-01 MSDS

Next, the plaintiffs "move to preclude any argument, evidence or testimony stating or implying that Chevron Phillips Employee Frank Zakrzewski said that there was 'no scientific basis' for the Medical Application Caution in the Marlex HGX-030-01 [MSDS.]" (Pls.' Mot. *in Limine* No. 3 [Docket 132], at 1). The plaintiffs contend that Bard has repeatedly mischaracterized Mr. Zakrzewski's testimony throughout the course of these MDLs and will continue to do so in the present case. However, a blanket exclusion of such argument, evidence, or testimony would be premature. If the plaintiffs object to a particular statement or exhibit regarding Mr. Zakrzewski, they are free to raise those issues at trial. Accordingly, the plaintiffs' Motion *in Limine* No. 3 is **DENIED**.

d. Other Lawsuits Against the Implanting Surgeon

Next, the plaintiffs "move the Court to preclude Bard from introducing evidence and/or argument that the implanting surgeon, Mitchell Nutt, M.D. [sic], negligently implanted the Avaulta medical device in other patients[.]" (Pls.' Mot. *in Limine* No. 4 [Docket 133], at 1) (emphasis omitted)). The plaintiffs explain that Bard intends to "allocate fault against Dr. Nutt, a non-party in the trial of this product liability claim," and they contend that evidence of "other lawsuits against Dr. Nutt" is irrelevant and likely to confuse and mislead the jury. (*Id.* at 2 (emphasis omitted)). Bard concedes that it does not intend to offer evidence of *other* patients' lawsuits against Dr. Nutt. (Bard's Opp. to Pls.' Mot. *in Limine* No. 4 [Docket 181], at 1). However, Bard still seeks to introduce evidence of lawsuits that Ms. Wise has filed against Dr. Nutt or evidence concerning injuries arising out of Dr. Nutt's care. (*Id.*). As discussed more fully *infra* related to the plaintiff's Motion *in Limine* No. 5, I **FIND** evidence of Ms. Wise's other

lawsuits relevant to Bard's defense of intervening cause. Accordingly, the plaintiffs' Motion *in Limine* No. 4 is **DENIED**.

e. Empty Chair Defense

Next, the plaintiffs seek to preclude Bard from asserting "an empty chair defense." (Pls.' Mot. *in Limine* No. 5 [Docket 170], at 1 (quoting *Doe v. Wal-Mart Stores, Inc.*, 558 S.E.2d 663 (W. Va. 2001))). The plaintiffs cite to both *Doe* and *Rowe v. Sisters of Pallottine Missionary Society*, 560 S.E.2d 491 (W. Va. 2001), in support of their argument that Bard has failed to meet its burden of proof regarding Dr. Nutt or the hospital's violation of the standard of care. (Pls.' Mot. *in Limine* No. 5 [Docket 170], at 1–2). In response, Bard notes that it has raised lack of causation, intervening cause, and contributory fault as affirmative defenses and contends that it has presented "ample evidence" supporting its position on alternative causation. (Bard's Opp. to Pls.' Mot. *in Limine* No. 5 [Docket 207], at 2).

In *Sydenstricker v. Mohan*, the West Virginia Supreme Court of Appeals ("WVSCA") found that the defendant was entitled to introduce evidence of a nonparty's negligence to establish the defense of intervening cause, which is recognized in West Virginia. 618 S.E.2d 561, 568 (W. Va. 2005) ("In order for Dr. Mohan to establish the defense of intervening cause, he had to be allowed to introduce evidence of Dr. Lucero's negligence, even if the evidence was inadmissible under *Rowe*."); *see also Mid-State Sur. Corp. v. Thrasher Eng'g, Inc.*, No. 2:04-0813, 2006 WL 1390430, at *11 (S.D. W. Va. May 16, 2006) (allowing the defendant to introduce evidence of non-party's fraud in light of the principles discussed in *Sydenstricker*). Accordingly, I **FIND** that Bard is entitled to introduce evidence of Dr. Nutt's or the hospital's fault—the "empty chair defense"—inasmuch as it tends to demonstrate that such fault served as an intervening cause of Ms. Wise's injuries, and the plaintiff's Motion *in Limine* No. 5 is

DENIED.

f. AUGS/SUFU SUI Sling Position Statement

Next, the plaintiffs move to exclude evidence related to the AUGS/SUFU position statements because they are irrelevant, litigation driven, and "admittedly unscientific." (Pls. Mot. *in Limine* No. 6 [Docket 171], at 1–2). First, I do not agree with the plaintiffs that these statements are entirely irrelevant to this case. The position statements challenged in this motion relate to more than merely mid-urethral slings in the treatment of SUI. (*See, e.g.*, AUGS & SUFU Position Statement [Docket 205-1], at 2 (stating "[p]olypropylene material is safe and effective as a surgical implant.")).

Second, I have previously denied motions *in limine* as to this issue. I explained:

> First, to the extent that the Position Statement is relied upon by an expert witness, it may be admissible under the learned treatise exception to the hearsay rule. *See* Fed. R. Evid. 803(18). Second, under Rule 703, experts are permitted to rely on otherwise inadmissible information provided that they "would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed. R. Evid. 703. Third, Ethicon's state of mind is relevant to the punitive damages claim, and "[a]n out-of-court statement that is offered to show its effect on the hearer's state of mind is not hearsay under Rule 801(c)." *United States v. Thompson*, 279 F.3d 1043, 1047 (D.C. Cir. 2002). Provided that Ethicon properly introduces this evidence, the plaintiffs' motion on this issue is **DENIED**.

Huskey v. Ethicon, Inc., No. 2:12-cv-5201, 2014 WL 3861778, at *2 (S.D. W. Va. Aug. 6, 2014); *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 505234, at *2 (S.D. W. Va. Feb. 5, 2014). Accordingly, in this case, the plaintiffs' Motion *in Limine* No. 6 is **DENIED**.

g. Other Manufacturers' Pelvic Repair Mesh Products and Unrelated Bard Product Experience

Lastly, the plaintiffs "move to preclude any argument, evidence, or testimony relating to Bard's [sic] other manufacturers' products and unrelated Bard product experience." (Pls.' Mot. *in Limine* No. 7 [Docket 172], at 1). This motion is both unduly vague and broad. An evidentiary

ruling on this issue depends on the particular content of the evidence and argument and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, the plaintiffs' Motion *in Limine* No. 7 is **DENIED**.

III. The Defendant's Motions *in Limine*

Many of Bard's motions *in limine* here are identical or substantially similarly to those raised in recent cases by Bard and other defendants. I have largely adopted my reasoning from those cases. In some instances, my increased familiarity with these issues and how they might arise at trial has allowed me to issue more substantive rulings than in earlier cases. In other instances, I still lack the necessary specificity and context to exclude certain evidence at this point in time.

a. Any Material Safety Data Sheet for Polypropylene Resin and the Manner by Which Bard Procured Polypropylene Resin from Suppliers

Bard seeks to preclude any evidence or argument regarding the Phillips Sumika Material Safety Data Sheet ("MSDS") and the methods by which Bard acquired polypropylene resin from its suppliers. Bard argues that (1) the plaintiffs reliance on the MSDS constitutes "improper hearsay use," (2) "nothing about the procurement of polypropylene resin goes to Plaintiffs' warnings or design claims," and (3) the "MSDS evidence poses an undue risk of jury confusion and prejudice." (Bard's Mot. *in Limine* No. 1 [Docket 175], at 1–3).

First, I **FIND** that evidence or argument as to the MSDS is admissible for several reasons. The MSDS falls within the hearsay exception found in Rule 803(17) as an "other compilation[] that [is] generally relied on by the public or by persons in particular occupations." Fed. R. Evid. 803(17). To the extent that the plaintiffs seek to offer the MSDS to show that the

statements within it "were made or that they had some effect on the future actions of a listener," or "for the more limited purpose of providing relevant context or background," the MSDS is not hearsay. *United States v. Castro–Lara*, 970 F.2d 976, 981 (1st Cir. 1992). To the extent that the plaintiffs introduce the statements in the MSDS through an expert witness, the statements fall within the hearsay exception found in Rule 803(18) as a "statement contained in a . . . pamphlet." Fed. R. Evid. 803(18). Finally, the MSDS falls within the residual hearsay exception under Rule 807.

Second, I **FIND** that evidence or argument as to the methods by which Bard acquired polypropylene resin is relevant as to the plaintiffs' substantive claims, as well as their claim for punitive damages. Accordingly, I **DENY** Bard's Motion *in Limine* No. 1.

b. Unrelated Business Issues, Investigations, Alleged Bad Acts, or Alleged "Illegal Activity"

Bard seeks to exclude "evidence concerning Bard's unrelated business activities, investigations, or alleged 'illegal activity.'" (Bard's Mot. *in Limine* No. 2 [Docket 175], at 4). Bard argues that this evidence is irrelevant, unfairly prejudicial, and impermissible character evidence. (*Id.* at 4–6).

In *Lewis*, this court did not admit evidence of unrelated "(1) criminal guilty pleas and fines . . . (2) state attorney general actions . . . (3) consent decrees with the U.S. Department of Justice or FDA . . . (4) settlements or fines with the U.S. Department of Justice or Securities and Exchange Commission . . . and (5) any investigations or proceedings by any political bodies or enforcement agencies . . . ." *See*, 2014 WL 505234, at *4–5. However, an evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or

testimony would be premature. Accordingly, Bard's motion *in limine* No. 2 is **DENIED**.

c. That Bard Owed or Breached an Independent Duty to Conduct Additional Testing or Inspection

Bard seeks to preclude any evidence or argument that it owed or breached an independent duty to conduct additional testing or inspection. (Bard's Mot. *in Limine* No. 3 [Docket 175], at 7). I agree that there is no independent claim for negligent testing or inspection at this point. However, evidence regarding Bard's testing or inspection generally, or lack thereof, may be relevant to whether Bard "knew or should have known" of the alleged dangers in the Avaulta products. An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, Bard's motion *in limine* No. 3 is **DENIED**.

d. Post-Implant Regulatory Communications and Developments

Bard argues initially that the plaintiffs "should be limited to presenting evidence as [to] the events that took place prior to [their] alleged injuries and that could be causally related to [their] claims." (Bard's Mot. *in Limine* No. 4 [Docket 175], at 11). Bard then argues that (1) regulatory developments cannot be used to establish causation; (2) the FDA's Public Health Notifications ("PHNs") and Advisory Committee Meeting ("ACM") are inadmissible hearsay; and (3) "[p]ost-implant regulatory evidence should be excluded under Rule 403." (*Id.* at 10–12).

The plaintiffs appear to concede that all FDA evidence should be excluded. (*See* Pls.' Resps. in Opp. to Bard's Mots. in Limine ("Pls.' Resps.") [Docket 197], at 11 ("The Court has repeatedly, correctly, ruled that FDA regulatory actions are excluded from these cases. This BARD MIL is merely the latest example of why the Court reached the correct conclusion in this

regard.")). Accordingly, consistent with my prior decisions in these MDLs, as well as in the present case, Bard's Motion *in Limine* No. 4 is **GRANTED**.

e. Bard's Decision to Stop Selling the Avaulta Products or Suggesting the Avaulta Products Were Recalled or Withdrawn

Bard seeks to preclude "evidence of or reference to the discontinuation of the manufacture and distribution of Avaulta products, including Avaulta Plus," as inadmissible under Rule 407. (Bard's Mot. *in Limine* No. 5 [Docket 175], at 13). Evidence of subsequent remedial measures is inadmissible to prove "negligence; culpable conduct; a defect in a product or its design; or a need for warning or instruction." Fed. R. Evid. 407. However, the evidence may be admitted "for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures." *Id.* In other words, the admissibility of such evidence depends on the context and method by which the plaintiffs seek to introduce it. Accordingly, I **DENY** Bard's Motion *in Limine* No. 5.

f. Foreign Regulatory Actions

Bard seeks to exclude "evidence of foreign regulatory action regarding Bard's Avaulta products." (Bard's Mot. *in Limine* No. 6 [Docket 175], at 16). Bard argues that such evidence is irrelevant "[b]ecause Ms. Wise was implanted with Avaulta Plus products in the United States," and such evidence carries "[t]he potential for undue prejudice . . . [that] far outweighs any probative value, would mislead and confuse the jury, and would waste time and judicial resources." (*Id.*). An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, Bard's motion *in limine* No. 6 is **DENIED**.

g. That Bard Owed or Breached a Duty to Warn Plaintiff Directly or Bard Owed or Breached a Duty to Train Plaintiff's Physician

Bard seeks to preclude any "claim or argument" that (1) "Bard owed and breached a duty to provide warnings to Ms. Wise directly" and (2) that "Bard owed and breached a duty to provide training to Dr. Nutt, the implanting physician." (Bard's Mot. *in Limine* No. 7 [Docket 175], at 18). The plaintiffs concede that Bard did not owe a duty to warn the plaintiff directly. (Pls.' Resps. [Docket 197], at 19). Accordingly, with regard to Bard's duty to warn the plaintiff directly, Bard's motion *in limine* is **GRANTED**. With regard to Bard's duty to train physicians, I have previously denied a similar motion. In *Lewis*, I ruled that even though Texas does not recognize a duty to provide training to physicians evidence or argument related to physician training might possibly be relevant for some other purpose, depending on the context and method by which it is introduced. *See* 2014 WL 505234, at *5. I see no reason to deviate from this ruling here. Therefore, Bard's motion to preclude evidence on the duty to train physicians is **DENIED**.[4]

h. Product Complaints, Adverse Event Reports, and Medical Device Reports Concerning Patients Other Than Plaintiff

Bard seeks to preclude "evidence of product complaints, adverse event reports (AERs), or Medical Device Reports (MDRs) . . . in an attempt to establish the mesh caused the alleged complications." (Bard's Mot. *in Limine* No. 8 [Docket 175], at 21). Bard argues three points: (1) product complaints, AERs and MDRs are inadmissible and hearsay; (2) the reports are not probative, relevant evidence of causation or notice; and (3) these documents are unfairly prejudicial. (*Id.* at 21–23). An evidentiary ruling on this issue depends on the particular content

[4] I note that West Virginia's law on the duty to train physicians is not entirely settled. *See Runyon v. Hannah*, No. 2:12-cv-1394, 2013 WL 2151235, at *7 (S.D. W. Va. May 16, 2013) ("Under West Virginia law, claims of negligent training and supervision are governed by general negligence principles. *See*[, *e.g.*,] *Pruitt v. W. Va. Dep't of Pub. Safety*, 664 S.E.2d 175, 179, 181–83 (W. Va. 2008) (allowing claims of negligent failure to train and supervise to proceed to trial); . . . ."). Regardless, whether West Virginia recognizes a duty to train physicians has no effect on the plaintiffs' negligence claims.

of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, Bard's motion *in limine* No. 8 is **DENIED**.

i. Other Lawsuits Involving Mesh

Bard moves to preclude "evidence of other lawsuits or claims involving mesh products—whether or not related to the Avaulta Plus or other Bard-manufactured products." (Bard's Mot. *in Limine* No. 9 [Docket 175], at 24). Bard argues that this evidence should be precluded because it is irrelevant under Federal Rule of Evidence 401, inadmissible hearsay, and unfairly prejudicial under Federal Rule of Evidence 403. (*Id.* at 24–26).

Having gained more familiarity with this issue, I have granted motions *in limine* in other cases to exclude evidence of other mesh lawsuits against the same defendant and other defendants. *See Eghnayem*, 2014 WL 5465741, at *8; *Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5445769, at *7 (S.D. W. Va. Oct. 22, 2014); *Lewis*, 2014 WL 505234, at *5–6. In *Eghnayem*, I explained:

> [E]vidence of lawsuits is generally considered inadmissible hearsay. . . . Further, evidence of other lawsuits and the factual allegations therein is inadmissible under Rule 403. Although other lawsuits may ultimately show that the [product] is defective, the jury must still find that the [product] caused [the plaintiff's] injuries. Evidence of other lawsuits is likely to confuse and mislead the jury from that task, and it is highly prejudicial to [the defendant].

2014 WL 5465741, at *8 (quoting *Lewis*, 2014 WL 505234, at *6). I apply this reasoning to the evidence challenged by Bard here. Therefore, I **GRANT** Bard's Motion *in Limine* No. 9.

j. Marketing or Promotional Activity That Did Not Impact Plaintiff's Prescribing Physician

Bard seeks to preclude "any evidence or argument concerning any marketing or

promotional activity that did not affect the decision making of Ms. Wise's implanting physician." (Bard's Mot. *in Limine* No. 10 [Docket 175], at 27). Bard focuses largely on the relevancy of these materials to the plaintiffs' failure-to-warn claims. These materials may be relevant to the plaintiffs' other claims, including negligence and punitive damages. Any such relevancy will be determined at trial pursuant to any appropriate objections at that time. Accordingly, Bard's Motion *in Limine* No. 10 is **DENIED**.

k. That Avaulta Products Can Cause Persistent Delayed Healing, Dehiscence, Abscess or Other Alleged Complications Not Experienced by Plaintiff

Bard seeks to preclude "evidence or argument regarding alleged complications purportedly caused by Bard's Avaulta products" that were not experienced by Ms. Wise. (Bard's Mot. *in Limine* No. 11 [Docket 175], at 30). Evidence of complications that no plaintiff experienced is irrelevant and lacking in probative value. For the claims that require evidence of injury (strict liability for failure to warn, strict liability for design defect, and negligence), only the injuries experienced by the complainant are relevant. Strict liability for failure to warn, for instance, requires the plaintiff to show that the inadequate warning "made the product not reasonably safe" and that "the defect was the probable cause of *her* injuries." *Ilosky v. Michelin Tire Corp.*, 307 S.E.2d 603, 609 (W. Va. 1983) (emphasis added). Strict liability for defective design also hones in on the plaintiff's injuries. *See Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 682 (W. Va. 1979) (explaining that the cause of action in product liability cases is "whether the defect was the proximate cause of *plaintiff's* injury") (emphasis added). With respect to negligence, the inquiry is whether the defendant "proximately caused the injuries *of the plaintiff*." *Strahin v. Cleavenger*, 603 S.E.2d 195, 205 (W. Va. 2004) (emphasis added). Accordingly, evidence that the Avaulta causes injuries not experienced by the plaintiff has little probative value. Moreover, elaborating on injuries that the plaintiff did not incur risks "needless

presentation of cumulative evidence." Fed. R. Evid. 403. Therefore, Bard's Motion *in Limine* No. 11 is **GRANTED**.

l. Bard's Intent, Motives, and Ethics

Bard seeks to preclude evidence "pertaining to Bard's intent, motives, and ethics, including . . . evidence or argument at trial suggesting that Bard had a financial motive to downplay potential risks associated with the use of the Avaulta products." (Bard's Mot. *in Limine* No. 12 [Docket 175], at 33). An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, Bard's Motion *in Limine* No. 12 is **DENIED**.

m. Pain, Suffering, and/or Impact of Plaintiffs' Alleged Injuries on Their Children, Family, or Friends

Bard seeks to exclude "evidence of the pain, suffering, and/or the impact of Ms. Wise's alleged injuries on [the plaintiffs'] friends, children, and family members . . . ." (Bard's Mot. *in Limine* No. 13 [Docket 175], at 36). Bard argues that this evidence is irrelevant. Contrary to Bard's assertion, however, this evidence is relevant to the plaintiffs' damages insofar as the plaintiffs have allegedly suffered adverse effects on their relationships and ability to enjoy activities with their friends, children, and family members. Any such relevancy will be determined at trial pursuant to appropriate objections at that time. Accordingly, Bard's Motion *in Limine* No. 13 is **DENIED**.

n. Relationship Between Polypropylene or the Avaulta Plus System and Cancer

Bard seeks to preclude "any evidence or suggestion that the Avaulta Plus System or polypropylene mesh can cause cancer." (Bard's Mot. *in Limine* No. 14 [Docket 175], at 37).

Given that there is no evidence Ms. Wise suffered from sarcomas or cancer as a result of the Avaulta products, this evidence has little to no relevance. Furthermore, references to cancer often evoke juror sympathy increasing the risk of unfair prejudice. *See, e.g.*, *United States v. Brooke*, 4 F.3d 1480, 1486 (9th Cir. 1993); *Jackson v. Johns–Manville Sales Corp.*, 750 F.2d 1314, 1321 (5th Cir. 1985). Accordingly, Bard's Motion *in Limine* No. 14 is **GRANTED**.

o. Inflammatory and Prejudicial Statements or Evidence During Trial

Bard seeks to "(1) limit Plaintiffs' use of inflammatory statements in opening statements and during trial; and (2) preclude Plaintiffs from presenting deposition testimony, whether video or transcribed, during opening statements." (Bard's Mot. *in Limine* No. 15 [Docket 175], at 41). The parties agree that opening statements provide the jury with an introduction to the case and allow the parties to outline the facts they seek to prove at trial. To the extent Bard identifies inflammatory statements as those "concerning Bard's alleged corporate culture or motivations," they appear to be alleged facts related to punitive damages. (*Id.* at 39).

With respect to deposition testimony, I **FIND** that the use of video clips during opening statements is precluded as to all parties, but I will not preclude the parties from summarizing or quoting deposition testimony in their opening statements. To the extent Bard relies on Federal Rule of Evidence 106, I note that quoting from or summarizing deposition testimony during an opening statement is not "introducing" the deposition. *See* Wright et al., 21A Fed. Prac. & Proc. Evid. § 5075 n.46 (2d ed.) ("Should the lawyer read from the document during opening statements, the opponent could not, we think, invoke Rule 106 to require introduction at that point.").

Bard's additional claim that "Plaintiffs should be prohibited from presenting inflammatory and misleading descriptions as evidence or argument during the trial" amounts to

little more than a broad request that I order the plaintiffs to follow the Federal Rules of Evidence. Admissibility of statements Bard considers unfairly inflammatory or prejudicial will be determined at trial pursuant to any appropriate objections at that time.

Accordingly, Bard's Motion *in Limine* No. 15 is **GRANTED** with respect to the use of video clips during opening statements and **DENIED** otherwise. To be clear, the preclusion of the use of video clips extends to both parties.

p. The Parties' Litigation Conduct

Bard seeks to preclude any argument or evidence concerning:

> (A) Evidence of mediation or settlement negotiations;
> (B) Bard's designation of any documents as confidential or any suggestion that Bard's actions were improper or an attempt to keep certain documents secret; and
> (C) Evidence of Bard's litigation conduct and of Court rulings such as motions *in limine* or objections during discovery.

(Bard's Mot. *in Limine* No. 16 [Docket 175], at 42). With respect to evidence of mediation or settlement negotiations, Bard is correct that under Federal Rule of Evidence 408(a), such evidence is not admissible "either to prove or disprove the validity or amount of a disputed claim or to impeach by a prior inconsistent statement or a contradiction." Fed. R. Evid. 408(a). However, under Rule 408(b), this evidence may be admitted for other purposes. With respect to evidence concerning Bard's litigation conduct and court rulings, although it appears highly unlikely that these issues would become relevant at trial, it is impossible to determine the relevancy of any argument or evidence concerning these issues at this stage. Accordingly, I **FIND** that a blanket exclusion of such evidence and argument would be premature at this time, and therefore I **DENY** Bard's Motion *in Limine* No. 16 with respect to evidence of mediation or settlement negotiations and evidence concerning Bard's litigation conduct and court rulings.

As for evidence concerning the designation of confidential documents, "[w]hether a party

designates a document as confidential during the litigation process is absolutely irrelevant." *Lewis*, 2014 WL 505234, at *7. The jury will be instructed at trial to disregard the confidential marking on documents. Therefore, I **GRANT** Bard's Motion *in Limine* No. 16 with respect to this issue.

q. Bard's Financial Information or Condition

Bard seeks to preclude evidence of its "financial information or condition, including profitability, employee compensation, and employment decisions." (Bard's Mot. *in Limine* No. 17 [Docket 175], at 45). I note that I denied Bard's motion for summary judgment on the issue of punitive damages, and bifurcated the trial into two phases, where liability (for both compensatory and punitive damages) and the amount of compensatory damages will be determined in phase one, and the amount of punitive damages, if any, will be determined in phase two. Evidence of Bard's financial information and condition are certainly relevant as to the amount of punitive damages and therefore relevant to phase two of the trial. However, I **FIND** the probative value of allowing evidence of financial status during the first phase of the trial is substantially outweighed by the danger of confusing the issues or misleading the jury. Fed. R. Evid. 403. Such evidence is more appropriately considered during the second phase of the trial, which, if necessary, would focus on the amount of punitive damages. Accordingly, Bard's Motion *in Limine* No. 17 is **GRANTED in part** and **DENIED in part**.

r. Health of Plaintiff's Parents and Plaintiff's Role in Caring for her Parents

Bard seeks to preclude "evidence of Ms. Wise's parents' health" and plaintiffs' role in caring for her parents under Federal Rule of Evidence 403(b). (Bard's Mot. *in Limine* No. 18 [Docket 175], at 46–48). In response, the plaintiffs struggle to identify with precision why such evidence is relevant to Ms. Wise's claims that she was injured by a product manufactured by

Bard. They do not argue Ms. Wise has been unable to continue caring for her parents as a result of her alleged injury, but they assert she delayed her own medical needs in order to tend to her parents. (*See* Pls.' Resps. [Docket 197], at 44–45). The mental and physical health of Ms. Wise's family members may well be substantially more prejudicial than probative, but it is difficult for me to rule on the admissibility of such evidence at this time without knowing the plaintiffs' specific purpose for offering it. Accordingly, Bard's Motion *in Limine* No. 18 is **DENIED**.

IV. Conclusion

For the reasons set forth above, the plaintiffs' Motion *in Limine* No. 1 [Docket 128] is **GRANTED**; the plaintiffs' Motion *in Limine* No. 2 [Docket 129] is **DENIED**; the plaintiff's Motion *in Limine* No. 3 [Docket 132] is **DENIED**; the plaintiffs' Motion *in Limine* No. 4 [Docket 133] is **DENIED**; the plaintiffs' Motion *in Limine* No. 5 [Docket 170] is **DENIED**; the plaintiffs' Motion *in Limine* No. 6 [Docket 171] is **DENIED**; and the plaintiffs' Motion *in Limine* No. 7 [Docket 172] is **DENIED**.

Additionally, Bard's Motions *in Limine* No. 4, 9, 11, and 14 [Docket 175] are **GRANTED**; Bard's Motions *in Limine* Nos. 15, 16, and 17 [Docket 175] are **GRANTED in part** and **DENIED in part**; and the following of Bard's Motions *in Limine* are **DENIED**: 1–3, 5-8, 10, 12, 13 and 18 [Docket 175].

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 6, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE